REMARKS

Support for Amendments

Support for the amendment to claim 1 is found in claim 5, canceled herewith, and the specification at page 10, lines 10-12. No new matter is introduced by this amendment.

The Office Action

Claims 1, 5-14, 35, and 39-49 are pending in this application. All pending claims stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 4,470,371 ("the '371 patent), in view of U.S. Patent No. 5,789,208 ("the '208 patent).

Rejections Under 35 U.S.C. § 103 (a)

Claims 1, 5-14, 35, and 39-49 stand rejected under 35 U.S.C. § 103(a) as obvious over the '371 patent in view of the '208 patent. Specifically, the Examiner asserts that the '371 teaches polyclonal antibodies and antibody mixtures for the treatment of allergies, wherein the antibodies are, *inter alia*, formulated for topical nasal administration and are free of the allergen to which the antibody is reactive (Office Action mailed January 28, 2003, page 3, lines 7-9). The Examiner further asserts that it would have been *prima facie* obvious for a person of ordinary skill to substitute recombinant polyclonal antibodies, made according to the methods of the '208 patent, for the polyclonal antibodies used in the '371 patent. It is further asserted that one would have been motivated to combine these references because the use of recombinant antibodies, according to the '208 patent, solves the problem of limited antibody supply. Applicants respectfully disagree.

In order to establish a prima facie case of obviousness, the Examiner must demonstrate that the prior art teaches or suggests every claim limitation. M.P.E.P. § 2142.

Applicants first point out that claim 1, the sole independent claim, has been amended to require that the pharmaceutical composition be free of allergen to which the polyclonal antibody is reactive. As presently amended, Applicants respectfully submit that every claim limitation is not taught or suggested by the prior art.

Contrary to the Examiner's assertion, the '371 patent does not teach a pharmaceutical composition that is free of the allergen to which the antibody is reactive. The '371 patent discloses pharmaceutical compositions that contain "a mixture of an allergen and antibody thereto" (column 3, lines 32-33). Further, the '371 patent teaches away from the use of an allergen-free composition. For example, the '371 patent states (column 4, lines 45-52; emphasis added):

> In practicing the present invention, there are <u>essentially</u> three steps, namely:
> (1) identification of the allergen and preparation of the antibody thereto;
> (2) <u>formation of the mixture of allergen and antibody to make a composition of the invention</u>; and
> (3) administration of the composition to the patient.

The Examiner, by referring to column 8, lines 15-33 to demonstrate that the antibody compositions are allergen free, mischaracterizes the '371 patent. The passage to which the Examiner refers in an intermediate step in the preparation of the pharmaceutical composition. The section relates to the purification of immunoglobulins from the patient's blood using an immunoadsorbent column. At no time does the '371 patent suggest administering the eluant to the patient. Applicants respectfully direct the Examiner's attention to column 8, lines 52-60. Under the heading "Preparation of the complexes and injectable compositions," the '371 patent describes antibody-antigen mixing, dilution, and sterilization prior to injection. It is clear that the '371 patent never contemplates administering a polyclonal antibody in the absence of allergen.

The prior art, therefore, fails to teach or suggest administering an allergen-free antibody-containing composition for the treatment of allergy. Thus, even if we accept arguendo the Examiner's assertion that an artisan would have been motivated to substitute the recombinant antibodies made by the methods of the '208 patent for the antibodies used in the '371 patent, the artisan would not have formulated those antibodies into an allergen-free composition, as required by the instant claims. Accordingly, this rejection should be withdrawn.

Withdrawal of Finality

Applicants also request reconsideration of the decision to make this action Final, because the circumstances of this case fall squarely within the Exceptions to Finality of the Office Action, as set forth in MPEP § 706.07(a). This section states (emphasis added):

> Under present practice, second or any subsequent action on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set in 37 CFR 1.97(c) with the fee set forth in 37CFR 1.17(p).

The Final Office Action (mailed January 28, 2003) includes a rejection on prior art not previously of record, i.e., the rejection of all pending claims under 35 U.S.C. § 103(a) in view of the '371 patent. The '371 patent was not cited by the Examiner in the previous Office Action (mailed March 7, 2002) and, therefore, is newly cited art. In response to that Office Action, Applicants narrowed the scope of the antibodies that could be used in the claimed compositions from antibodies "capable of ... binding to an allergen" to antibodies "capable of ... binding to proteins or epitopes derived from an inhaled, ingested, or airborne allergen." The newly entered rejection based on the '371 patent is

unrelated to "proteins or epitopes derived from an inhaled, ingested, or airborne allergen" and could have been properly asserted in the earlier Office Action. This new rejection is not "necessitated by applicant's amendment" because any rejection based of the '371 patent was applicable to the unamended claims. Thus, the § 103(a) rejection, in view of the '371 patent, is a new ground of rejection that estops the Examiner from making the second Office Action a Final Office Action. Applicants therefore request that the Finality of the Action be removed.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is requested. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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